



SEP 21 2001

Rec'd 1/27/03 jib

Mr. Shiming Han
Vice President
Wealth Express Industrial Ltd.
Block B1, 19/F Kailey Industrial Center
12 Fung Yip St. Chai Wan
Hong Kong

Dear Mr. Han:

This letter is in response to your completed notification, dated July 9, 2001 you submitted to the Food and Drug Administration (FDA), making a submission for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act). Your letter notified FDA of your intent to market a product containing a new dietary ingredient named "Hirudo powder." FDA received your complete submission on

Correction → July 11, 2000.
2001

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully evaluated the information in your submission. Your submission contains evidence of history of use and other information that you assert is an adequate basis to conclude that a dietary supplement product containing Hirudo powder will reasonably be expected to be safe. However, the agency has significant concerns about the evidence on which you rely to support your conclusion.

You state that Hirudo powder has been used in traditional Chinese medicine for thousands of years. As a medicine in China, hirudo is the desiccated body of *Thitmania pigra* Whitman, *Hirudo nipponica* Whitman or *Whimania acranulata* Whitman belonging to the Hirudo family. You provided information on the historical use of Hirudo in traditional Chinese medicine as well as in modern medicine (for venous insufficiency). However, your

955-0316

CR1

submission does not include information on the post-marketing history of these products in China, including adverse effect monitoring, that could contribute to demonstrating a basis to support that its use in the United States as a dietary supplement will be expected to be safe.

The Chinese literature (Exhibits A-C) referenced in your submission state that the dosage for internal use of Hirudo powder varies from 1.5 to 9 g a day used alone or in combination with other medicines. Treatment duration when mentioned is usually 4 to 6 weeks. The proposed label recommends a daily use of 900 mg Hirudo powder which is lower than those recorded levels used in traditional Chinese medicine (Exhibits A-C). However, you did not provide information on the safety of its long-term use, which is relevant to the typical use of dietary supplements by consumers.

In addition, you did not provide any information on the source of the material(s) from which this new dietary ingredient will be derived nor the procedure for its preparation in order to ensure its purity. Information that accompanied your submission did not provide an adequate basis to judge the quality of the new dietary ingredient.

The saliva of medicinal leeches contains many compounds (hirudin and other protein inhibitors, enzymes, etc.) that have anticoagulation, clot dissolving, and antiplatelet aggregation properties (Exhibits C-D). Therefore, the potential health risks from the use of this product in persons who are already taking drugs or other products which may adversely interact with Hirudin powder needs to be addressed. The agency also has significant concerns about the potential risk of serious adverse effects with use of Hirudo powder for consumers who have certain diseases or conditions. For example, Hirudo has abortive properties and can be used for abortion. Use during pregnancy and in patients with “blood vacuity but no blood stasis” are not recommended in traditional Chinese medicine (Exhibits A-C). However, no restriction of use of the dietary supplement with respect to physiological conditions or age of the consumer is noted in your submission.

Finally, please be advised that any representation that a product is intended for the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals suggests that it is a drug, as defined in 21 U.S.C. § 321(g)(1)(B), and would be subject to regulation under the drug provisions of the Federal Food, Drug and Cosmetic Act. All drugs must be approved by FDA before they can be marketed in the U.S.

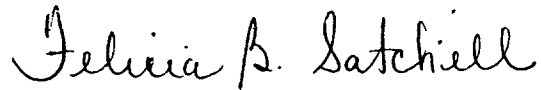
For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that Hirudo powder, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains the new dietary ingredient Hirudo powder for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Page 3 – Mr. Shiming Han

Your submission will be kept confidential for 90 days from the date of receipt, and after November 14, 2000, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification will not be made available to the public.

Should you have any questions concerning this matter, please contact me at (202) 205-4168.

Sincerely yours,

A handwritten signature in cursive script that reads "Felicia B. Satchell".

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements